DUR Board Meeting
October 1st, 2007
Heritage Center
Rooms A and B
1pm

August 31st, 2007

The next North Dakota Drug Utilization Review (DUR) Board Meeting will be held October 1st, 2007 at 1:00pm

Heritage Center
Rooms A and B
612 East Blvd
Bismarck, ND

Please remember to silence all pagers and cell phones prior to the start of the meeting.

North Dakota Medicaid
DUR Board Meeting
Agenda
Heritage Center
Rooms A and B
October 1st, 2007
1pm

1. Administrative items
   - Travel vouchers
   - Board Members Sign In

2. Old Business

• Review and approval of minutes of 08/20/07 meeting	Chairman
• Budget update	Brendan
• Review of Antineoplastic Agents	HID
• Review of Antiretroviral Agents	HID
• Review of ADHD	HID
• Review of High Cost Medications	HID
• Yearly PA Review of DAW-1	HID

3. New Business

• Review of Antidepressant Agents	HID
• Criteria Recommendations	Brendan
• Upcoming meeting date/agenda	Chairman

4. Adjourn — Chairman

Please remember to turn all cellular phones and pagers to silent mode during the meeting.

Drug Utilization Review (DUR) Meeting Minutes
August 20th, 2007

Members Present: Albert Samuelson, Patricia Churchill, Cheryl Huber, Norman Byers, Carrie Sorenson, Todd Twogood, Greg Pfister, Scott Setzepfandt, Bob Treitline, John Savageau, Kim Krohn, Jeffrey Hostetter.
Medicaid Pharmacy Department: Brendan Joyce, Gary Betting
HID Staff Present: Candace Rieth
Members Absent: Leann Ness and Carlotta McCleary.

Chairman, C. Huber, called the meeting to order at 1:00pm. New members were introduced to the Board. C. Huber asked for a motion to approve the minutes from the June 4th, 2007 meeting. A. Samuelson moved that the minutes be approved and G. Pfister seconded the motion. The chair called for a voice vote to approve the minutes, which passed with no audible dissent.

Budget Update
B. Joyce made available charts showing figures for utilizer per month and average prescription cost per month. On average, the cost per prescription per month is approximately fifty-three dollars. The average spent per member per month is approximately one-hundred and fifty dollars.

Review of Amrix
At the June meeting, a motion and second was made to place Amrix on prior authorization. No new information was presented. C. Huber called for a voice vote and the motion passed with no audible dissent. Motion passed to place Amrix on prior authorization.

Synagis Review
B. Joyce updated the Board regarding Synagis utilization. The Department would like to develop a patient registry for Synagis. Potential Synagis patients would be submitted to the Department by physicians. A registry would allow the Department to track Synagis patients and utilization. It would also allow the Department to track patients that should receive Synagis and do not. Currently, there is no system in place to track Synagis prescriptions and it appears that some patients may be getting missed in areas outside of Bismarck. At the June meeting, a motion and second was made to require a registry for Synagis patients. C. Huber called for a voice vote and the motion passed with no audible dissent. Motion passed to require a registry for Synagis. Board members requested an update on Synagis, including city data, be placed on the winter agenda for review.

Review of Tekturna
Tekturna is a new antihypertensive medication that is the first direct renin inhibitor approved by the FDA. Criteria for approval would be similar to the ARBs as there is no outcome data to suggest Tekturna should be used first line before ACE inhibitors or ARBs. There was public comment by Dana Meier, representing Novartis. She reviewed Tekturna related prescribing information with the Board and stated that new head to head trials will be available in September. K. Krohn asked for clarification regarding the wording on the PA form. She suggested that the wording on the prior authorization forms be simplified to make the forms easier to fill out. B. Treitline stated that the prior authorization forms have been the same since 2005 and he would suggest that they not change. Since the prior authorization forms and the Tekturna prior authorization are two separate topics, C. Huber called for a voice vote to place Tekturna on prior authorization. The motion passed with no audible dissent. B. Joyce said that he would review the wording included on the prior authorization forms and the Board could discuss it further at the October meeting.

Review of Xopenex HFA
The final discontinuation date for CFC inhalers is December 31, 2008. With the absence of these inhalers, HFA inhalers will be the only option for albuterol/levalbuterol in the near future. With the switch from CFC inhalers to HFA inhalers, the Department anticipates an increase in total claims cost of at least 170,000 dollars a year. The Department would like to group the albuterol HFA and levalbuterol HFA products together and choose the preferred product based on the cheapest HFA, post-rebate. Unfortunately, the Department is unable to disclose rebate dollars to the Board to show the major difference between the HFA albuterol and HFA levalbuterol products. New information was presented to the Board that showed city distribution of providers writing prescriptions for Xopenex HFA. Most prescriptions for Xopenex HFA are prescribed by one physician in Minot and in Bismarck. B. Joyce mentioned that the Department should not make a policy exemption for such small numbers of physicians. A motion was made by T. Twogood to remove the age exemption, add levalbuterol wording to the prior authorization form, and approve the prior authorization of Xopenex HFA. C. Sorenson seconded the motion. C. Huber called for a voice vote and the motion passed with no audible dissent. Motion passed to place Xopenex HFA on prior authorization.

Review of Ketek
In light of recent FDA warnings, the Department would like to monitor utilization of Ketek. A motion and second was made at the June meeting to place Ketek on prior authorization. C. Huber called for a voice vote and the motion passed with no audible dissent. Motion passed to place Ketek on prior authorization.

Legislative Update
House Bill 1422 restricts placing the following classes of medications on Prior Authorization. These include AIDS, Cancer, Anti-psychotics, Anti-depressants, ADHD and Mood-Stabilizers. Over the next two years, the DUR Board will be responsible for reviewing these classes and making recommendations to the Department regarding the plan of action the Board would take, if any. The DUR Board recommendations will be reported, periodically, to the Legislative Council.

Oral Antineoplastic Review
At the June meeting, A. Samuelson suggested getting a consult from one of the Oncology physicians currently prescribing to North Dakota Medicaid patients. B. Joyce will contact these physicians for guidance regarding this class of medications. At this time, there is no new information to review and B. Joyce informed the Board members that this topic would be presented at a future meeting.

HIV/AIDS Review
At the June meeting, T. Twogood suggested getting a consult from one of the Infectious Disease doctors currently prescribing to North Dakota Medicaid patients. B. Joyce met with Dr. Martin, an Infectious Disease doctor in Bismarck. He works with the ND Department of Health and the Ryan White program (a federally funded program that provides HIV/AIDS medications to patients not on Medicaid). He sits on the Ryan White P&T Committee with other North Dakota Infectious Disease physicians and they have a formulary for the Ryan White program. Dr. Martin reviewed the ND Medicaid utilization data and stated that all utilization appears to follow the Ryan White formulary.

B. Joyce asked Dr. Martin if the law restricting prior authorizations on antiretrovirals was necessary, and Dr. Martin said that no law was needed if the Board had no intention of placing these medications on prior authorization. He also said such a law could keep immediate action from happening if a physician started moving away from the Ryan White formulary or practice standards. B. Joyce confirmed with Dr. Martin that the Ryan White P&T Committee would be willing to exert peer pressure on anyone prescribing in an outlier fashion (if that ever happens).

A motion was made by B. Treitline and seconded by N. Byers that the Board take the view of Dr. Martin. This would mean that the restrictions would be allowed to sunset as related to antiretrovirals and no further action would be taken by the DUR Board as the Board has no intent to prior authorize any of the medications in this class. C. Huber called for a voice vote and the motion passed with no audible dissent.

High Cost Medications
House Bill 1459 directs the Department to review expensive medical procedures for prior authorizations. The Department would also like to extend this review to medications. This would allow reconciliation of data to determine incorrect billings. The Department would like for the Board to review utilization data and make suggestions on how best to monitor these products. The Board would like for more information to be provided on this topic including a minimum claim amount of three thousand dollars, strength of medication, quantities dispensed and days supply. This topic will be discussed at a later meeting.

Yearly Review of Prior Authorization
Once a year, the Board reviews products that were placed on prior authorization. This allows the Board a chance to review the prior authorization forms and criteria. Growth Hormone/IGF-1 products were reviewed. No action will be taken regarding the Growth Hormone/IGF-1 form or criteria.

ADHD Review
The ADHD review is based on the 2007 legislative session requesting information on classes of medications that currently are exempt from prior authorization. B. Joyce reviewed utilization data of the ADHD meds. Based on post-rebate information, Adderall XR is the most cost effective choice between Adderall XR and Vyvanse; given that Vyvanse is simply a less abusable follow-on product to Adderall XR as Adderall XR approaches its patent expiration. B. Joyce relayed information regarding the prior authorization of Sed/Hypnotics. The Board chose to leave Ambien as preferred to maintain market share in anticipation of the generic becoming available and to keep market share from shifting to the follow-on product Ambien CR and other competitors. Due to the proactive nature of this decision, the Department is saving approximately 30,000 dollars a month with generic Ambien. B. Joyce stated the logic for the suggested prior authorization of Vyvanse is the same as used for Ambien.

B. Joyce asked the Board what their overall desired actions are for ADHD medications. T. Twogood stated that there is really nothing that would predict one ADHD medication would work better than another; therefore trying the most cost effective agent first would be a very valid approach. The Board stated that they would like to broaden the prior authorization stipulations and include step therapy and asked B. Joyce to bring such an approach back to the next meeting.

B. Treitline made a motion and N. Byers seconded that the Board should recommend prior authorizing Vyvanse as presented in the packet (therefore requesting that the law should be allowed to sunset in relation to ADHD medications). C. Huber called for a voice vote and the motion passed with no audible dissent.

Criteria Recommendations
The recommended RDUR criteria enclosed in the packet were developed from product information provided by the manufacturers and usually are consistent with new indications, new drugs added, new warnings, etc. These criteria will be added to the current set of criteria, and will be used in future DUR cycles. N. Byers moved to approve the new criteria and A. Samuelson seconded the motion. C. Huber called for a voice vote and the motion passed with no audible dissent.

Miscellaneous Items
Generic Zoloft is also saving the Department approximately 318,000 dollars a quarter. North Dakota Medicaid currently has a 68% generic utilization rate.

PhRMA contacting Board members
C. Sorenson and other Board members have received letters from Pfizer asking them to place smoking cessation products on the agenda for future meetings. B. Joyce stated that Pfizer has been told that current agendas are full while the Board reviews classes of medications for the legislative council and further requests of this fashion can be referred to him.

The next DUR board meeting will be October 1st, 2007. B. Joyce reviewed future agenda items. These include Antidepressants, ADHD, and Cancer. P. Churchill made a motion to adjourn the meeting and A. Samuelson seconded. Chair C. Huber adjourned the meeting at 4:15 pm.

ADHD Pricing Review

When reviewing ADHD agents, the Department takes in to account post-rebate pricing when determining the list of preferred agents. Once the net per unit cost is determined, DACON (daily average consumption) data is used to standardize all of the medications to net daily price. The following information is a result of this calculation.

Cost of Product (smallest to greatest)

Immediate Release ADHD products < Concerta < Metadate CD < Ritalin LA < Focalin XR < Concerta < Adderall XR < Metadate CD

<<< Daytrana and Strattera

391 Industry Drive • Auburn, AL 36832 • Phone: (334)502-3262 • Fax: (334) 466-6947
Auburn, Alabama • Jackson, Mississippi • Little Rock, Arkansas • Salisbury, Maryland

HEALTH INFORMATION DESIGNS

ADHD PA FORM

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires the use of one of the following products as first line ADHD therapy: Metadate CD, Adderall XR, Concerta, Focalin XR, or Ritalin LA.

****Note:***

- **Daytrana and Strattera require a Prior Authorization.**

Part I: TO BE COMPLETED BY PHYSICIAN

RECIPIENT NAME:	RECIPIENT MEDICAID ID NUMBER:
Recipient Date of birth: / /	
PHYSICIAN NAME:	PHYSICIAN MEDICAID ID NUMBER:
Address:	Phone: ( )
City:	FAX: ( )
State: Zip:	

REQUESTED DRUG:	**Requested Dosage:** (must be completed)

Qualifications for coverage:

❑ Failed ADHD therapy	Start Date:	Dose:
	End Date:	Frequency:

Physician Signature: Date:

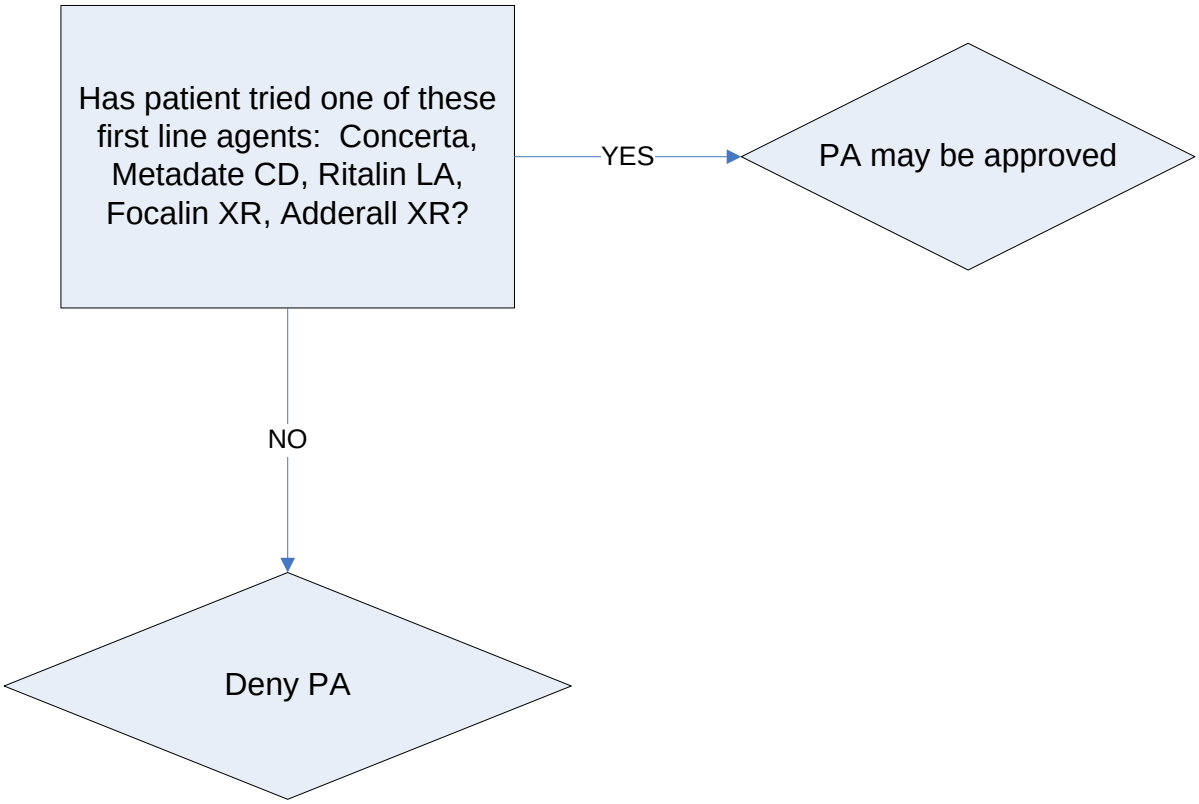
Part II: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:	ND MEDICAID PROVIDER NUMBER:
Phone:	FAX:
Drug:	NDC#:

Part III: FOR OFFICIAL USE ONLY

Date: / /		Initials: _____
Approved - Effective dates of PA:	From: / /	To: / /
Denied: (Reasons)		

North Dakota Department of Human Services
ADHD Authorization Algorithm



Cost of Product (smallest to greatest)

Immediate Release ADHD products < Concerta

< Metadate CD < Ritalin LA < Focalin XR

< Concerta < Adderall XR < Metadate CD

<<< Daytrana and Strattera

High Cost Drugs Claims Paid 01/01/2007 thru 07/24/2007

NDC Number	NDC Name	STRENGTH	Quantity Dispensed	Days Supply	Amt Paid
00003052411	SPRYCEL	70 MG	60	30	$ 4,385.73
00003052411	SPRYCEL	70 MG	60	30	$ 4,385.73
00003052411	SPRYCEL	70 MG	60	30	$ 4,385.73
00003052411	SPRYCEL	70 MG	60	30	$ 4,732.07
00003052411	SPRYCEL	70 MG	60	30	$ 4,267.48
00003052411	SPRYCEL	70 MG	60	30	$ 4,181.83
00003052411	SPRYCEL	70 MG	60	30	$ 4,732.07
00003052411	SPRYCEL	70 MG	60	30	$ 4,732.07
00003052411	SPRYCEL	70 MG	60	30	$ 4,732.07
00003052411	SPRYCEL	70 MG	60	30	$ 4,732.07
00003052411	SPRYCEL	70 MG	60	30	$ 4,732.07
00003052411	SPRYCEL	70 MG	60	30	$ 4,732.07
00003052411	SPRYCEL	70 MG	60	30	$ 4,732.07
00003052811	SPRYCEL	70 MG	60	30	$ 4,291.44
00003052811	SPRYCEL	70 MG	60	30	$ 4,732.07
00004003822	VALCYTE	450 MG	120	30	$ 4,120.18
00009513502	ZYVOX	600 MG	60	30	$ 4,180.89
00026037230	KOGENATE FS	1 IU	9,528	30	$ 10,385.60
00026037230	KOGENATE FS	1 IU	9,756	30	$ 9,756.20
00026037230	KOGENATE FS	1 IU	9,756	30	$ 10,634.00
00026037230	KOGENATE FS	1 IU	9,756	30	$ 10,634.00
00026037230	KOGENATE FS	1 IU	9,792	28	$ 10,673.30
00053813002	HELIXATE FS	1 IU	10,728	30	$ 11,371.70
00053813002	HELIXATE FS	1 IU	8,896	1	$ 9,880.16
00053813002	HELIXATE FS	1 IU	10,024	9	$ 11,132.24
00053813004	HELIXATE FS	1 IU	13,072	2	$ 13,992.64
00053813004	HELIXATE FS	1 IU	9,008	8	$ 9,644.16
00053813004	HELIXATE FS	1 IU	9,008	8	$ 9,644.16
00053813004	HELIXATE FS	1 IU	9,008	8	$ 9,644.16
00069098038	SUTENT	50 MG	28	28	$ 6,410.19
00069098038	SUTENT	50 MG	28	28	$ 6,463.73
00069098038	SUTENT	50 MG	28	28	$ 6,546.03
00074379902	HUMIRA	40 MG/0.8 ML	6	21	$ 4,457.38
00074433906	HUMIRA	40 MG/0.8 ML	6	14	$ 4,457.37
00075062300	LOVENOX	100 MG/ML	60	30	$ 4,181.00
00075062300	LOVENOX	100 MG/ML	60	30	$ 4,389.64
00075062300	LOVENOX	100 MG/ML	60	30	$ 4,389.64
00075062300	LOVENOX	100 MG/ML	60	30	$ 4,389.64
00075062300	LOVENOX	100 MG/ML	60	30	$ 4,389.64
00078043815	GLEEVEC	400 MG	30	30	$ 3,208.53
00078043815	GLEEVEC	400 MG	30	30	$ 3,208.53
00078043815	GLEEVEC	400 MG	30	30	$ 3,208.53
00078043815	GLEEVEC	400 MG	30	30	$ 3,208.53
00078043815	GLEEVEC	400 MG	30	20	$ 3,208.53
00078043815	GLEEVEC	400 MG	45	30	$ 4,812.00
00078043815	GLEEVEC	400 MG	45	30	$ 4,459.81

00078043815	GLEEVEC	400 MG	45	30	$ 4,459.81
00078043815	GLEEVEC	400 MG	45	30	$ 4,459.81
00078043815	GLEEVEC	400 MG	45	30	$ 4,812.00
00078043815	GLEEVEC	400 MG	45	30	$ 4,812.00
00078043815	GLEEVEC	400 MG	45	30	$ 4,812.00
00078043815	GLEEVEC	400 MG	45	30	$ 4,812.00
00078043815	GLEEVEC	400 MG	45	30	$ 4,812.00
00078043815	GLEEVEC	400 MG	45	30	$ 4,812.00
00078043815	GLEEVEC	400 MG	45	30	$ 4,812.00
00085136601	TEMODAR	100 MG	30	30	$ 5,045.16
00173075200	TYKERB	250 MG	150	30	$ 3,264.10
00173075200	TYKERB	250 MG	150	30	$ 3,264.10
00173075200	TYKERB	250 MG	150	30	$ 3,264.10
00469305130	AMBISOME	50 MG	30	10	$ 5,300.35
50242010040	PULMOZYME	2.5 MG/2.5 ML	150	30	$ 3,241.60
50242010040	PULMOZYME	2.5 MG/2.5 ML	150	30	$ 3,241.60
50242010040	PULMOZYME	2.5 MG/2.5 ML	150	30	$ 3,241.60
50242010040	PULMOZYME	2.5 MG/2.5 ML	150	30	$ 3,241.60
50242010040	PULMOZYME	2.5 MG/2.5 ML	150	30	$ 3,244.60
50242010040	PULMOZYME	2.5 MG/2.5 ML	150	30	$ 3,244.60
50242010040	PULMOZYME	2.5 MG/2.5 ML	150	30	$ 3,244.60
50242010040	PULMOZYME	2.5 MG/2.5 ML	150	30	$ 3,244.60
50242010040	PULMOZYME	2.5 MG/2.5 ML	150	30	$ 3,244.60
50242010040	PULMOZYME	2.5 MG/2.5 ML	150	30	$ 3,244.60
50242010040	PULMOZYME	2.5 MG/2.5 ML	150	30	$ 3,406.60
53905006501	TOBI	60 MG/ML	280	28	$ 3,629.80
53905006501	TOBI	60 MG/ML	280	28	$ 3,629.80
53905006501	TOBI	60 MG/ML	280	30	$ 3,629.80
53905006501	TOBI	60 MG/ML	280	30	$ 3,629.80
53905006501	TOBI	60 MG/ML	280	28	$ 3,421.60
53905006501	TOBI	60 MG/ML	280	28	$ 3,626.80
53905006501	TOBI	60 MG/ML	280	28	$ 3,626.80
53905006501	TOBI	60 MG/ML	280	28	$ 3,626.80
53905006501	TOBI	60 MG/ML	280	28	$ 3,629.80
53905006501	TOBI	60 MG/ML	280	28	$ 3,629.80
53905006501	TOBI	60 MG/ML	280	28	$ 3,626.80
53905006501	TOBI	60 MG/ML	420	28	$ 5,442.40
53905006501	TOBI	60 MG/ML	560	15	$ 7,252.00
53905006501	TOBI	60 MG/ML	280	28	$ 3,626.80
59572020594	THALOMID	50 MG	56	28	$ 3,810.34
59572020594	THALOMID	50 MG	56	28	$ 3,517.33
59572020594	THALOMID	50 MG	84	28	$ 6,220.20
59572020594	THALOMID	50 MG	56	28	$ 4,422.41
59572020594	THALOMID	50 MG	84	28	$ 6,725.61
59572021015	THALOMID	100 MG	28	28	$ 3,646.89
63004773101	H.P. ACTHAR	80 U/ML	10	33	$ 3,717.62
63004773101	H.P. ACTHAR	80 U/ML	10	30	$ 3,717.62
66215010106	TRACLEER	62.5 MG	60	30	$ 3,960.48
66215010106	TRACLEER	62.5 MG	60	30	$ 3,960.48
66215010106	TRACLEER	62.5 MG	60	30	$ 3,617.29

66215010106	TRACLEER	62.5 MG	60	30	$ 3,960.48
66215010106	TRACLEER	62.5 MG	60	30	$ 3,960.48
66215010106	TRACLEER	62.5 MG	60	30	$ 3,960.48
66215010106	TRACLEER	62.5 MG	60	30	$ 3,960.48
66215010106	TRACLEER	62.5 MG	60	30	$ 4,187.85
66215010106	TRACLEER	62.5 MG	60	30	$ 4,187.85
66215010106	TRACLEER	62.5 MG	60	30	$ 4,187.85
66215010206	TRACLEER	125 MG	60	30	$ 3,960.48
66215010206	TRACLEER	125 MG	60	30	$ 3,960.48
66215010206	TRACLEER	125 MG	60	30	$ 3,960.48
66215010206	TRACLEER	125 MG	60	30	$ 3,960.48
66215010206	TRACLEER	125 MG	60	30	$ 4,187.85
66215010206	TRACLEER	125 MG	60	30	$ 4,187.85

HEALTH INFORMATION DESIGNS

DAW-1 Claims June 2007

Drug	DAW Scripts
Synthroid	8
Tegretol	5
Klonopin	4
Orapred	3
Prozac	3
Coumadin	3
Dexedrine	2
Celexa	2
Climara	2
Ultram	2
Clozaril	2
Cardizem CD	1
Pediapred	1
Xanax	1
Tenex	1
Ritalin	1
Lo-Ovral	1
Adderall	1
Corgard	1
Ortho Tri-Cyclen	1
Mestinon	1
Pred Forte	1
Lithobid	1
Tofranil	1
Zarontin	1
Halcion	1
Lasix	1
Wellbutrin SR	1
Mysoline	1

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Dispense As Written PA Form

Clear Fields

Fax Completed Form to:
866-254-0761
For questions regarding this prior authorization, call
866-773-0695

North Dakota Medicaid requires that patients receiving a brand name drug, when there is a generic equivalent available, must first try and fail the generic product for one of the following reasons

- **The generic product was not effective**
- **There was an adverse reaction with the generic product**

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Physician Name			
Physician Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	Zip Code

Requested Drug	**Requested Dosage** (must be completed)	**Diagnosis for the request**

Qualifications for coverage:

☐ Failed generic equivalent	Start Date	End Date	Dose	Frequency
☐ Adverse reaction to generic equivalent (attach FDA Medwatch form) or contraindicated (provide description):				

☐ *I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.*

Physician Signature	Date

Part II: TO BE COMPLETED BY PHARMACY

Pharmacy Name			ND Medicaid Provider Number
Telephone Number	Fax Number	Drug	NDC #

Part III: FOR STATE USE ONLY

Date Received	CSP MD ☐ Yes ☐ No CSP Pharmacy ☐ Yes ☐ No	Daily Units Bypass Units ☐ Yes ☐ No	Req App	CLM Limit
Approved - Effective dates of PA From: / / To: / /			Approved By	
Denied (Reasons)				

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
4TH QUARTER 2007

Recommendations	*Approved*	*Rejected*

1. Pregabalin / Thiazolidinediones _____ _____

Alert Message: Caution should be exercised when using Lyrica (pregabalin) and a thiazolidinedione (rosiglitazone or pioglitazone) concurrently. Both pregabalin and the thiazolidinediones have been shown to cause weight gain and peripheral edema, possibly exacerbating or leading to congestive heart failure.
Conflict Code: DD – Drug/Drug Interaction
Drugs/Disease:

Util A	Util B	Util C
Pregabalin	Pioglitazone	
	Rosiglitazone	

References:
Facts & Comparisons, 2007 Updates
Micromedex Healthcare Series, DrugDex Drug Evaluations, 2007.
Lyrica Prescribing Information, Nov. 2006, Pfizer Inc.

2. Pregabalin / Heart Failure _____ _____

Alert Message: Lyrica (pregabalin) should be used with caution in patients with New York Heart Association (NYHA) Class III or IV cardiac status. During clinical trials dose-related weight gain and peripheral edema were reported with pregabalin use. These adverse effects may exacerbate heart failure.
Conflict Code: DC – Drug (Actual Disease) Precaution
Drugs/Disease:

Util A	Util B	Util C
Pregabalin	Heart Failure	

References:
Facts & Comparisons, 2007 Updates
Micromedex Healthcare Series, DrugDex Drug Evaluations, 2007.
Lyrica Prescribing Information, Nov. 2006, Pfizer Inc.

3. Pregabalin / High Dose (Diabetic Neuropathy) _____ _____

Alert Message: Lyrica (pregabalin) may be over-utilized. The manufacturer's recommended dose for patients with diabetic peripheral neuropathy is 300 mg per day. Higher doses have not been shown to confer significant additional benefit and are less well tolerated.
Conflict Code: HD – High Dose
Drugs/Disease:

Util A	Util B	Util C (Inclusive)
Pregabalin		Diabetic Peripheral Neuropathy

Max Dose: 300 mg/day
References:
Facts & Comparisons, 2007 Updates
Micromedex Healthcare Series, DrugDex Drug Evaluations, 2007.
Lyrica Prescribing Information, Nov. 2006, Pfizer Inc.

Recommendations	*Approved*	*Rejected*

4. Pregabalin / High Dose (Postherpetic Neuralgia) _____ _____

Alert Message: Lyrica (pregabalin) may be over-utilized. The manufacturer's recommended maximum dose for patients with postherpetic neuralgia is 600 mg per day. In view of the dose-dependent adverse effects and the higher rate of treatment discontinuation caused by adverse reactions, dosing above 300 mg per day should be reserved only for those patients who have ongoing pain and are tolerating 300 mg daily.
Conflict Code: HD – High Dose
Drugs/Disease:

Util A	Util B	Util C (Inclusive)
Pregabalin		Postherpetic Neuralgia

Max Dose: 600 mg/day
References:
Facts & Comparisons, 2007 Updates
Micromedex Healthcare Series, DrugDex Drug Evaluations, 2007.
Lyrica Prescribing Information, Nov. 2006, Pfizer Inc.

5. Pregabalin / High Dose (Partial Onset Seizures) _____ _____

Alert Message: Lyrica (pregabalin) may be over-utilized. The manufacturer's recommended maximum dose for patients with partial onset seizures is 600 mg per day.
Conflict Code: HD – High Dose
Drugs/Disease:

Util A	Util B	Util C (Inclusive)
Pregabalin		Partial Onset Seizures

Max Dose: 600 mg/day
References:
Facts & Comparisons, 2007 Updates
Micromedex Healthcare Series, DrugDex Drug Evaluations, 2007.
Lyrica Prescribing Information, Nov. 2006, Pfizer Inc.

6. Pregabalin / High Dose (Renal Impairment) _____ _____

Alert Message: Lyrica (pregabalin) is primarily renally eliminated and the dose should be adjusted in patients with renal impairment. The maximum recommended dose of pregabalin in patients with a CrCl ≥ 60 mL/min is 600 mg/day while patients with a CrCl of 30 to 60 mL/min should not exceed 300 mg/day. Patients with a CrCl of 15 to 30 mL/min should not exceed 150 mg/day and patients with a CrCl of <15 mL/min should receive a maximum of 75 mg/day.
Conflict Code: HD - High Dose
Drugs/Disease:

Util A	Util B	Util C
Pregabalin		Renal Impairment

Max Dose: 75 mg/day
References:
Facts & Comparisons, 2007 Updates
Micromedex Healthcare Series, DrugDex Drug Evaluations, 2007.
Lyrica Prescribing Information, Nov. 2006, Pfizer Inc.

Recommendations	*Approved*	*Rejected*

7. Antidepressants / Therapeutic Appropriateness _____ _____

Alert Message: All antidepressant-containing medications increase the risk of suicidal thinking and behaviors (suicidality) in children, adolescents, and young adults. Patients being treated with antidepressants for any indication should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior especially during the initial months of drug therapy, or at times of dose changes.
Conflict Code: TA – Therapeutic Appropriateness
Drug/Diseases

Util A	Util B	Util C
Isocarboxazid		
Phenelzine		
Tranylcypromine		
Imipramine		
Amitriptyline		
Nortriptyline		
Desipramine		
Protriptyline		
Fluvoxamine		
Amoxapine		
Trimipramine		
Doxepin		
Maprotiline		
Trazodone		
Bupropion		
Fluoxetine		
Clomipramine		
Sertraline		
Paroxetine		
Venlafaxine		
Nefazodone		
Citalopram		
Mirtazapine		
Escitalopram		
Duloxetine		

Age Range: 0 – 24 years of age

References:
FDA News: FDA Proposes New Warning About Suicidal Thinking, Behavior in Young Adults Who Take Antidepressant Medications, May 2, 2007. Available at: http://www.fda.gov/bbs/topics/NEWS/2007/NEW01624.html